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SUBJECT: HEALTH MINISTER READIES NEW DRUG REGISTRATION RULES, PLANS
TO PUT REGISTRATION ON-LINE

Sensitive but unclassified. Please handle accordingly.

¶1. (SBU) SUMMARY On November 23, newly appointed Ministry of Health Assistant Minister for Pharmaceutical Affairs Kamal Sabra told FCS and Econ counselor that the MOH would soon put drug registration on-line and that the new drug registration rules are almost finished. The department's new facilities considerably limit public access to ministry offices and have substantially improved security. Sabra asked for help from the FDA in training Egyptian inspectors and said that Ministry El Gabaly is very pleased about plans for the USPTO-sponsored counterfeit drug seminar planned for January 2009. END SUMMARY.

¶2. (SBU) On November 23, FCS and econ counselors, accompanied by FCS's pharmaceutical expert, paid an introductory call on the Ministry of Health's newly appointed Assistant Minister for Pharmaceutical Affairs, Kamal Sabra. Sabra, who started at the ministry about six weeks ago, is a former pharmacy professor at Cork University in Ireland, has also worked in the pharmaceutical industry. He was joined by Samia Salah, head of the Drug Policy and Planning Center. This department has recently moved into new offices. According to Salah, the new offices provide a better work environment for her staff. The public, including pharmaceutical companies and their agents, are confined to the main floor and are not permitted in the offices of the ministry staff. Salah said her staff is now able to work undisturbed, and industry representatives no longer have free rein in the various departments. This has considerably improved overall security; the lack of security in the office has long been a concern to firms wanting their proprietary information safeguarded properly. Controlling public access is important, as the bureaucratic burden of the application process is enormous. According to Sabra, the MOH has received 4000 licensing applications in the past nineteen months, and have recently decided to open on Saturdays, in an effort to deal with the crowds.

NEW REGISTRATION RULES

¶3. (U) New drug registration rules are in draft, and should be ready shortly. The MOH will guarantee that new products will be approved within six months of the date of the submission of the complete application. This is about half the time that the current registration requires. Registration is not of course guaranteed, Sabra cautioned, as part of the approval process is a pharma-economic analysis and some drugs are simply too expensive for the Egyptian market. The legislation will establish certain reference countries, including the US, EU, Australia and Japan. If drugs have received approval in these countries, from the FDA in the case of the U.S., the MOH will do less analysis and batch inspection. In addition, a visit to the factory, for example, will not be required.

¶4. (U) In response to a question about exclusive marketing rights, Sabra contended that the period in the US begins when the application is made, not when it was approved. He seemed to be arguing that dating the exclusive period from the application date was appropriate. At any rate, he said that since the registration process would be significantly speeded up, this should not be such

an issue.

REGISTRATION PROCESS

15. (SBU) Sabra announced that the MOH will move the entire registration process on-line, including required forms and regulations, in English. He expects companies will apply for registration online, rather than in person. Also, all drugs currently licensed in Egypt will also be listed on the site. Sabra expects that putting the application process on line will solve a major source of information leaks for companies. Many companies hire agents to represent them in the application process. These agents often represent more than one pharmaceutical firm at a time. Sabra accused the agents of copying the technical documents and sharing them with other firms. He also said, in response to a comment that MOH personnel taking registration documents often did not seem to know the rules, that the agents for the companies were just as bad. He personally refuses to deal with the agents, and only deals directly with the companies in resolving any problems. As with many other ministries in Egypt, on-line registration is an effective tool at fighting corruption, at least at the working level. Companies gain access to the information they need, and can file all their forms, without having to deal with low-level MOH bureaucrats.

FACTORY INSPECTION

16. (SBU) Another area of concern is the quality of Egyptian inspectors. In the US and elsewhere, Sabra said, inspectors do a good job of looking at the factories and so regulators don't worry about individual products coming out of those factories. Here in Egypt, he has no confidence in the factory inspections, and so must test all the products individually, and relatively often, because he

is not sure of the quality of the production process. This is more of a problem for the local manufacturers, rather than the multinationals, Sabra acknowledged, because the multinationals must meet internal standards and are therefore to some extent self-regulating. An improved inspection system would improve efficiency overall, he said.

COMPLAINTS ABOUT THE MULTINATIONALS

17. (SBU) Sabra also noted he has evidence that virtually all of the multinational companies are selling direct to doctors. This, he said, is illegal and unethical. For example, his ministry found pamphlets in doctors offices aimed at patients who, if they filled out a survey, were offered a free refill. He also said the companies offer sales incentives to pharmacists. Some of the firms, he said, had provided evidence that other firms were doing this but in several cases he had information that the firms making these accusations were also engaged in the practices. In one case, the ministry had raised the price of certain medications to the consumer, at some political cost and to a chorus of media criticism. The same day the MOH had raised prices, Sabra said, the American firm offered pharmacists a twenty percent discount for the purchase of one of the medications for which the price had increased. The media got a hold of the invoice, with the discount, dated the same day of the price increase. This, he said, had been very politically difficult for the ministry.

18. (SBU) Sabra said that he planned to raise this issue with the multinationals later the same day. He said that he will offer them the opportunity to negotiate a formula, similar to ones in Europe, whereby the companies agree to a standard reduction in the price of medications once their exclusive marketing period is over and generics are also available. This, he said, was far preferable to negotiating price cuts on a case by case basis, and would give him some political cover for price hikes on name brand medications still covered by exclusive marketing rights. Otherwise, he said, the option was a unilateral cut in reference prices.

19. (SBU) Salah said Cialis has been approved for the Egyptian market, but that the patent is still pending. Lilly had told us that the patent office has yet to send to MOH a notification letter of the applications; Salah said it was not up to the MOH. For his part, Sabra was somewhat dismissive of the patent issue, on the grounds that many companies didn't bother filing for patents but

once they did, they did not focus on completing the application and getting it through the system. He commented that Cialis has gotten its market registration and should be receiving its patent shortly.

LOOKING AHEAD

¶10. (SBU) The minister is looking forward to the counterfeit drug conference organized by USTPO in January in Cairo5 is planning to participate himself, and will encourage key officials and business people to attend. Sabra said he would be interested in having some FDA inspectors visit Egypt, perhaps in connection with the conference, to provide training for his inspectors. He proposed that they do a joint inspection of two factories in Egypt, a multinational and a local pharmaceutical manufacturer, to give his inspectors some hands on training.
Scobey